

2007

The Patent End Game: Evaluating Generic Entry into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives

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Jeremiah Helm, *The Patent End Game: Evaluating Generic Entry into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives*, 14 MICH. TELECOMM. & TECH. L. REV. 175 (2007).

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COMMENT

THE PATENT END GAME: EVALUATING GENERIC ENTRY INTO A BLOCKBUSTER PHARMACEUTICAL MARKET IN THE ABSENCE OF FDA INCENTIVES

*Jeremiah Helm**

Cite as: Jeremiah Helm, *The Patent End Game: Evaluating Generic Entry into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives*, 14 MICH. TELECOMM. TECH. L. REV. 175 (2007), available at <http://www.mttl.org/volfourteen/helm.pdf>

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INTRODUCTION

Generic drugs play an important role in the American system of health care. Most anticipate that the entry of these drugs into the market will lower prices and thereby increase treatment options for consumers. To stimulate generic entry, the Food and Drug Administration currently offers a period of marketing exclusivity to the first firm that gains approval for a generic version of a branded drug. During this 180-day period, only two firms can sell versions of the drug: the original, branded

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drug maker and the first approved generic firm. After the period of exclusivity expires, other generic firms are free to enter the market.

In this Comment, I question whether the 180-day period of generic exclusivity benefits society. Using prescription drug sales data collected by IMS Health for the antibiotic Augmentin, I conduct an empirical analysis that suggests that the 180-day period of exclusivity is unnecessary to induce generic entry into a blockbuster drug market, and is thus potentially harmful to consumers. This Comment first describes the legal background surrounding the entry of generic drugs into the market. It then explains the statutory exemption that makes Augmentin an especially good model system for considering the need for the generic exclusivity incentive. Finally, this Comment analyzes generic and branded sales data to determine the effect of generic entry on the price of the branded drug and, more importantly, the average price paid by consumers.

A. Legal Background

The Food and Drug Administration (FDA) serves as the gatekeeper between pharmaceutical companies and the drug-consuming public. It is charged with ensuring the safety and efficacy of all new drug products brought to market.¹ There are two main ways that a drug can gain FDA approval and be brought to market.² First, if the drug is a novel product, the developer must submit it to the FDA using a New Drug Application (NDA).³ Second, if the drug is a generic version of an existing drug, the generic drug maker can submit an Abbreviated New Drug Application (ANDA).⁴

The most important difference between an NDA and an ANDA is the amount and cost of the data required to gain FDA approval. An NDA requires the applicant to conduct expensive clinical trials.⁵ In contrast, an ANDA allows a generic drug manufacturer to avoid conducting its own clinical trials by relying on the data submitted in the branded firm's NDA.⁶ The firm filing an ANDA only needs to provide data that proves

1. 21 U.S.C. § 355 (Supp. V 2005).

2. There are other ways drugs can be brought to market, for example, the Orphan Drug Act. However, this Comment focuses solely on NDAs and ANDAs.

3. 21 U.S.C. § 355(b).

4. 21 U.S.C. § 355(j).

5. 21 C.F.R. § 314.50(d)(2), (5)(2007). *See also* FDA, *Drug Approval Application Process*, <http://www.fda.gov/cder/regulatory/applications/> (last visited Sept. 9, 2007) (describing the NDA approval process).

6. *See* FDA, *Abbreviated New Drug Application*, <http://www.fda.gov/cder/regulatory/applications/ANDA.htm> (last visited Sept. 9, 2007) (describing the ANDA process). The generic firm, however, does not actually have access to the branded firm's data. *See* Rebecca S.

its product is bioequivalent to the branded product. The cost of applying for an ANDA, including the bioequivalence testing, is approximately \$600,000.⁷ In stark contrast, one study estimates that the average cost of bringing a new drug to market via an NDA, including clinical trials, exceeds \$800,000,000.⁸ Thus, it is approximately 1300 times more expensive to bring a drug to market using an NDA than it is using an ANDA.

Branded pharmaceutical manufacturers can recoup the large investment needed to bring a drug to market because of the exclusivity granted by patent protection.⁹ During this exclusivity period, the branded firm has a monopoly on the sale of the pharmaceutical product, which allows the firm to price the drug above competitive levels. This enables the branded firm to recoup the considerable upfront investment necessary to bring a drug to market. In contrast, generic firms require a relatively small upfront investment to enter the market for a drug once patent protection has expired. These firms, however, face a competitive market because they do not enjoy the exclusivity granted by patent protection.

Society benefits from the current system in two ways. First, society benefits from the branded firm's innovation. This is the classic justification for granting patent rights,¹⁰ with the added bonus that the FDA approval process certifies the safety and efficacy of the drug.¹¹ Second, upon generic entry into the market, society gains as generic firms compete with the branded manufacturer, drive the price down to competitive levels, and reduce deadweight loss. When crafting public policy, society must be cognizant of both these benefits and balance them appropriately.

Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007), available at <http://www.mtlr.org/volthirteen/eisenberg.pdf>.

7. David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. ECON. & STAT. 37, 38 (2005) (estimating the cost of an ANDA at \$603,000 in the "early 1990s").

8. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003). This article also includes estimates of the mean cost for each phase of clinical trials. *Id.* at 162.

9. Branded pharmaceutical firms can also receive an extension on their product's patent term of up to five years, reflecting the time needed for product approval. 35 U.S.C. § 156 (Supp. IV 2004).

10. Patent law represents a bargain between the innovator and the public. In exchange for disclosure of the details of an invention, the inventor is granted market exclusivity for a limited number of years. *See, e.g.,* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974) (citing Universal Oil Prods. Co. v. Globe Oil & Refining Co., 322 U.S. 471, 484 (1944)) (noting that disclosure is "the quid pro quo of the right to exclude").

11. The approval process serves to screen out unsafe drugs, but it is somewhat less than perfect. *See, e.g.,* Barbara Martinez et al., *Merck Pulls Vioxx From Market After Link to Heart Problems*, WALL ST. J., Oct. 1, 2004, at A1 (describing the safety problems encountered by users of the FDA approved drug Vioxx).

Generic entry to market was not always an inexpensive proposition. Before 1984 the current ANDA process did not exist, and a firm had to conduct its own clinical trials to gain approval for a generic version of a drug. This was a major barrier to generic entry because a generic firm spending the money for a clinical trial would, at best, share duopoly profits with the branded pharmaceutical maker already in the market. Moreover, because each subsequent generic entrant pushes the price of the drug down further, market entry would become progressively less appealing. The consequence of the barrier to entry was that before 1984, a market for a drug was usually not competitive, even after the expiration of patent protection.¹²

In 1984, Congress moved to ameliorate the barrier to generic entry and to stimulate competition by passing the Hatch-Waxman Act.¹³ The Hatch-Waxman Act has two aspects relevant to the issue of generic entry. First, it allows generic firms to piggyback on the branded firm's proprietary clinical trial data, which is submitted during the initial NDA process.¹⁴ Instead of having to conduct the extensive and expensive clinical trials itself, after Hatch-Waxman, a generic firm must only establish that its drug's composition is bioequivalent to the branded drug to gain FDA marketing approval.¹⁵ This change dramatically reduced the cost of entry for generic firms, from millions of dollars to thousands of dollars.¹⁶

Second, to ensure that generic entry occurs in a timely fashion, the Hatch-Waxman Act also includes an exception from patent infringement for experiments related to the preparation of an application for drug approval.¹⁷ In fact, the Supreme Court has interpreted this exception to

12. An important exception to the pre-1984 barrier to entry for generic firms was 21 U.S.C. § 357, which exempted antibiotics from the need to prove safety and efficacy. Until it was repealed in 1997, antibiotics were approved under section 357. 21 U.S.C. § 357 (*repealed* by Food and Drug Modernization Act of 1997, Pub. L. No. 110-115, 11 Stat. 2296 (1997)).

13. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (1994 & Supp. III 1997)).

14. 21 U.S.C. § 355(j) (Supp. V 2005).

15. *Id.* In fact, the FDA is explicitly directed *not* to consider safety and efficacy when examining an ANDA. See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 189 (1999) ("[The Hatch-Waxman Act] is a unique piece of legislation because it actually ties the hands of a regulatory agency . . . by providing specifically that FDA can require only bioavailability studies for ANDAs.").

16. In one study, the mean cost of conducting clinical trials was found to exceed \$120 million. DiMasi et al., *supra* note 8, at 162. Thus, the Hatch-Waxman Act reduced the cost of generic entry by approximately 99.5%. *Id.*; Reiffen & Ward, *supra* note 7, at 38.

17. See 35 U.S.C. § 271(e)(1) (2000) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States . . . a patented invention . . . solely for uses *reasonably related* to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." (emphasis added)).

allow for more than just research directly related to an ANDA application.¹⁸ As a result, a generic firm can establish bioequivalence and prepare its application for approval before the patent on the branded drug molecule has expired and bring it to market immediately after patent expiration.

B. *The Paragraph IV Certification and 180 days of Generic Exclusivity*

While the Hatch-Waxman Act lowers the barrier for generic entry into the market for a drug, it also includes provisions that the branded pharmaceutical industry can use to postpone generic entry.¹⁹ Although generic firms are free to prepare their application for entry to the market before the expiration of the branded firm's patent, they cannot actually bring the drug to market unless they include a certificate in their applications stating that, to the best of their knowledge, all of the relevant patents have expired, are invalid, or will not be infringed.²⁰ Branded firms must submit a list of all patents protecting a given therapeutic molecule to the FDA,²¹ which then lists the patents in a publication called the Orange Book.²² Generic firms who desire to enter the market then have two options: they can wait for the patents to expire, or challenge the patents' validity in court.²³ Because litigation is costly, and

18. See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206 (2005) (The § 271(e)(1) exemption may include "experimentation on drugs that are not ultimately the subject of an FDA submission . . . [and the] use of patented compounds in experiments that are not ultimately submitted to the FDA."). The Court also noted that § 271(e)(1) was not restricted to uses related to ANDA filings. See *id.* ("Congress did not . . . create an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug.").

19. The most obvious of these is the patent extension portion of the Hatch-Waxman Act. 35 U.S.C. § 156 (Supp. IV 2004). This is a giveback to the patent owner reflecting the extensive time needed to initially ferry the drug through the FDA approval process, and will not be discussed further in this Comment.

20. 21 U.S.C. § 355(j)(2)(A)(vii) (Supp. V 2005).

21. 21 U.S.C. § 355(b)(1).

22. The FDA does not consider the validity of the listed patents when listing them in the Orange Book. See *Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information. The agency believes that its scarce resources would be better utilized in reviewing applications rather than reviewing patent claims."); *Abbreviated New Drug Application Regulations*, 54 Fed. Reg. 28872, 28910 (July 10, 1989) ("In deciding whether a claim of patent infringement could reasonably be asserted . . . the agency will defer to the information submitted by the NDA applicant.").

23. Under this scenario, the actual case is brought by the patent holder for infringement by the generic firm. 35 U.S.C. § 271(e)(2) (2000). This can lead to interesting settlements wherein the patent owner *pays the infringer* to settle the suit. The potential anticompetitive nature of these exit payments has been extensively commented upon. See, e.g., FED. TRADE COMM'N, *GENERIC DRUG EXPIRATION PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (2002) ("FTC Study").

society prefers the early entry of generic drugs, the Hatch-Waxman Act offers an incentive for generic firms to initiate litigation to invalidate suspect patents by filing an ANDA based on "paragraph IV" certification.²⁴

Paragraph IV certification gives a bounty for invalidating patents listed by the branded pharmaceutical firm in the Orange Book: the first generic firm to successfully bring its drug to market gets 180 days of exclusivity during which no other generic firm can enter the market.²⁵ The value of this bounty can be considerable because the generic firm only competes with the branded version of the drug during the 180-day period. In addition, the generic firm has a considerable amount of discretion in deciding when to trigger the 180-day exclusivity period,²⁶ and can thus strategically plan to maximize its profits. After the 180-day period has run, other generic firms are free to enter the market as soon as they gain FDA approval for their own ANDA applications.

Once a paragraph IV infringement lawsuit is filed, the FDA approval process for the generic drug is stayed for a maximum of thirty months while the litigation takes place.²⁷ At this point, a generic firm faces two related barriers to entry. First, it must gain FDA approval, which the FDA will only grant after the expiration of the 30-month stay or a final judgment on patent validity by the district court.²⁸ Second, it must address the patents listed in the Orange Book to avoid liability for patent infringement. Even if the generic firm wins at the district court level, thereby opening the way for FDA approval, an appellate court may still find the relevant patents valid upon appeal, and the generic firm will be liable for infringement.²⁹

24. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Under paragraph IV, the generic firm certifies "with respect to each patent [listed in the Orange Book] . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" *Id.*

25. 21 U.S.C. § 355(j)(5)(B)(iv). During the 180-day period of exclusivity, the FDA will not approve another ANDA for the approved product. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(aa).

26. 21 U.S.C. § 355(j)(5)(B)(iv).

27. 21 U.S.C. § 355(j)(5)(B)(iii).

28. "[I]f before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—(aa) the date on which the court enters judgment reflecting the decision" 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa).

29. If the litigation finishes before the 30-month stay has run, a generic firm is free to bring its product to market. Similarly, if the litigation has yet to finish after thirty months, the generic firm holding the 180-day period of exclusivity may choose to bring its product to market before the end of litigation. Of course, in the latter situation, where the generic firm is guaranteed 180 days of exclusivity, it makes little sense to risk patent liability with an early launch of the generic. Thus, a generic firm is likely to wait until the end of litigation and all

C. Paragraph IV Approval Without Infringement Action

A branded pharmaceutical firm obviously benefits from the 30-month stay that results from bringing a suit against the first firm to file a paragraph IV ANDA. In some situations, however, the branded firm chooses not to file suit within its 45-day window. There are a number of reasons why the branded firm might choose not to trigger the 30-month stay. The main reason is that an old version of the statute allowed the first generic applicant to prevent all other generic firms from entering the market if a) the branded firm did not file suit, and b) the generic firm did not bring a product to market.³⁰ Under the old statute, if a drug firm files no lawsuit and the first firm fails to bring a product to market, then the 180 days of market exclusivity would never have been triggered, and the FDA could not approve *any* other generic applications. Though the current statute forecloses this possibility by giving the generic firm a limited amount of time to bring an approved drug to market,³¹ it was previously possible for the initial generic firm to stay out of the market forever, thereby keeping all other generic firms out of the market as well.³² This has the potential for anticompetitive results, particularly when the first generic filer makes a deal with the branded incumbent to stay out of the market.³³

D. Augmentin as a Case Study

The transition period when a branded drug goes off patent is incredibly important. Each side in the branded/generic interaction has a considerable amount to gain as well as a considerable amount to lose during this time period. The uncertainty surrounding generic entry at the end of patent life provides the opportunity for both the branded and generic firms to engage in a variety of strategic behaviors to maximize their profits.

This Comment considers the strategic behavior surrounding the expiration of the patents protecting the blockbuster drug Augmentin. Augmentin is the brand name of an antibiotic (amoxicillin/clavulanic acid) marketed by GlaxoSmithKline (Glaxo) and first approved for sale by the FDA in 1984. The Augmentin story departs from either of the

appeals before entering the market, regardless of how long it takes, as long as they are guaranteed exclusivity.

30. FTC Study, *supra* note 23, at 61–62.

31. See 21 U.S.C. § 355(j)(5)(D)(i)(I).

32. One case under the old regime suggested that a declaratory judgment action brought by a later filing generic firm that is dismissed for lack of a case or controversy is a “court decision” for the purpose of triggering the 180-day period of exclusivity for the original generic filer. See *Teva Pharm. USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999).

33. See generally FTC Study, *supra* note 23.

two typical methods of generic entry described above: Augmentin was originally approved by the FDA under 21 U.S.C. § 357,³⁴ and not under 21 U.S.C. § 355. An antibiotic approved under section 357, which includes all antibiotics approved before 1997, was not subject to the Hatch-Waxman Act and therefore does not receive the same administrative protections as a drug approved under section 355. Thus, Augmentin has no Orange Book patent listing, no paragraph IV certification, and, most importantly for the purposes of this discussion, no 180-day period of exclusivity.³⁵

Since paragraph IV certification was not available for Augmentin, this drug presents an interesting opportunity to test the hypothesis that 180 days of exclusivity is unnecessary to induce generic entry. Using empirical data to establish the behavior of the relevant firms at the end of patent exclusivity,³⁶ I argue that there is no need to induce generic firms to enter a newly available market. In addition, I observe that granting 180 days of exclusivity is likely to significantly postpone, and not hasten, generic entry, which leads to longer periods of super-competitive retail prices for consumers and extended periods of deadweight loss for society. Finally, I note that sequential entry by generic firms might facilitate oligopoly pricing by generic firms. The strategic pricing behavior of the relevant generic and branded firms is explored.

E. *The Augmentin Story*

In some ways, the Augmentin story is typical. The original patents protecting Augmentin were set to expire in the summer of 2002, and Glaxo moved to protect its market position by obtaining additional patents.³⁷ Augmentin-related patents filed many years before were finally approved by the Patent Office in 2000 and 2001. Since these patents were filed pre-TRIPS, the protection offered by the newly issued patents extended through 2018.

34. 21 U.S.C. § 357 was repealed in November 1997. Applications for antibiotics are now made under section 355. The initial application for an antibiotic under section 357 was called a "Form 5" and required studies equivalent to a full NDA. Bruce N. Kuhlik, *Industry Funding of Improvements in the FDA's New Drug Approval Process*, 47 FOOD & DRUG L.J. 483, 491 n.55 (1992).

35. See Stuart M. Pape, *Market Exclusivity Under the Drug Price Competition and Patent Term Restoration Act of 1984—The Five Clauses*, 40 FOOD DRUG COSM. L.J. 310, 315–16 (1985) (stating that antibiotics do not qualify for Hatch-Waxman protection).

36. The data used in this Comment were obtained from IMS Health. IMS Health provides data on drug prescription and pricing to the pharmaceutical industry. Its data is generated through surveys of more than ninety percent of the U.S. prescription market.

37. *Geneva Pharm., Inc. v. GlaxoSmithKline, PLC*, 213 F. Supp. 2d 597, 601 (E.D. Va. 2002).

TABLE I
RELEVANT AUGMENTIN PATENTS

PATENT IN SUIT	DATE OBTAINED	DATE INVALIDATED
4,525,352	June 25, 1985	July 19, 2002
4,529,720	July 26, 1985	July 19, 2002
4,560,552	December 24, 1985	July 19, 2002
6,218,380	April 17, 2001 ³⁸	February 25, 2002
ORIGINAL PATENTS	DATE OBTAINED	DATE EXPIRED
4,441,609	April 10, 1984 (Crowley)	April 10, 2001 (Crowley)
4,367,175	January 4, 1983 (Fleming)	January 4, 2000 (Fleming)

Without the protection of an Orange Book listing, however, the only barrier to generic entry was the threat of infringement litigation stemming from the newly granted Glaxo patents. To eliminate this barrier, several generic firms sued for declaratory judgment that the patents were invalid.³⁹ In two separate opinions, the district court found that Glaxo's patents were invalid for double patenting.⁴⁰ Glaxo subsequently appealed the district court's decision to the Federal Circuit.⁴¹

F. Generic Response to District Court Invalidation

The district court decisions invalidating Glaxo's patents were handed down on February 25, 2002, and July 19, 2002. At the time the patents were invalidated, Geneva was the only firm with approval for its generic version of Augmentin (Table 2). However, Teva and Ranbaxy, two large generic drug manufacturers, were also parties in the Glaxo suit. Thus, Geneva could reasonably anticipate that other companies would bring generic versions of Augmentin to the market in the near future.

38. Note that this patent was actually issued after Geneva filed its application for generic Augmentin with the FDA.

39. If Glaxo had been able to list these patents in the Orange Book and then sued the first approved generic, thereby triggering the 30-month stay, a declaratory judgment suit would not be allowed. If Glaxo had simply declined to sue the first approved generic, then a declaratory judgment suit is possible. Thus, this aspect of the Augmentin story is similar to the second path that a generic takes to market.

40. *Geneva Pharm., Inc. v. GlaxoSmithKline, PLC*, 189 F. Supp. 2d 377 (E.D. Va. 2002); *Geneva*, 213 F. Supp. 2d 597.

41. *Geneva Pharm., Inc. v. GlaxoSmithKline, PLC*, 349 F.3d 1373 (Fed. Cir. 2003).

TABLE 2
DATE OF APPROVAL AND MARKET ENTRY OF GENERIC AUGMENTIN

APP. NO.	DATE APPROVED	MARKET ENTRY	STRENGTH	APPLICANT
65063	March 14, 2002	July, 2002	875MG	Geneva (Novartis)
65064	March 15, 2002	July, 2002	500MG	Geneva (Novartis)
65065	April 18, 2002	July, 2002	200MG	Geneva (Novartis)
65065	April 18, 2002	July, 2002	400MG	Geneva (Novartis)
65066	June 5, 2002	July, 2002	200MG/5ML	Geneva (Novartis)
65102	September 17, 2002	January, 2003	875MG	Ranbaxy
65096	October 29, 2002	4th Q, 2002	875MG	Teva
65101	October 30, 2002	4th Q, 2002	500MG	Teva
65109	November 4, 2002	January, 2003	500MG	Ranbaxy
65093	November 21, 2002	January, 2003	875MG	Lek (Novartis) ⁴²
65117	November 27, 2002	January, 2003	500MG	Lek (Novartis)
65098	December 16, 2002	January, 2003	200MG/5ML	Lek (Novartis)
65098	December 16, 2002	January, 2003	400MG/5ML	Lek (Novartis)
65132	March 19, 2003		200MG/5ML	Ranbaxy
65132	March 19, 2003		400MG/5ML	Ranbaxy
65066	June 5, 2003		400MG/5ML	Geneva (Novartis)
65161	December 3, 2003		200MG	Ranbaxy
65161	December 3, 2003		400MG	Ranbaxy

The possibility of impending competition in the generic market led Geneva to take an unorthodox step.⁴³ Instead of waiting for a final judgment on the validity of Glaxo's patents from the Federal Circuit, Geneva decided to bring generic Augmentin to the market immediately after the district court's July 19 decision.⁴⁴ Even without paragraph IV certification and the accompanying 180-day bounty, Geneva took advantage of its early FDA approval to gain a period of market exclusivity. Geneva's move took advantage of its status as the first approved generic and also exploited the risk averse nature of some of its competitors: though Ranbaxy received FDA approval for a generic version of Augmentin in September 2002, it delayed launch of the drug until January 2003 because it feared potential infringement liability.⁴⁵ In fact, it appears that

42. Note that Geneva and Lek were subsidiaries of the same parent company, Novartis. For the purposes of later discussions on the number of generic entrants, I treat Geneva and Lek as effectively one firm. Thus, in 2003 I discuss three generic firms instead of four generic firms participating in the Augmentin market.

43. A. Maureen Rouhi, *Beyond Hatch-Waxman*, 80 CHEM. & ENG'G NEWS at 53-59, September 23, 2002, available at <http://pubs.acs.org/cen/coverstory/8038/8038biogenics2.html>.

44. *Id.*

45. See EPP News Bureau, *RLL May Corner 15% of Market for Generic Augmentin Suspension*, EXPRESS PHARMA PULSE, Mar. 27, 2003, available at <http://www.expresspharmaonline.com/20030327/corpmon1.shtml> ("While Ranbaxy was the second

Ranbaxy only brought generic Augmentin to market because Teva followed Geneva's lead in marketing generic Augmentin before the Federal Circuit decided the appeal.⁴⁶

As a result of its "at risk" market entry, Geneva enjoyed a period of "exclusivity" from July 2003 through October 2003.⁴⁷ During this four-month period, retail sales of Geneva's generic Augmentin totaled \$124 million. The willingness of Geneva, and its parent company Novartis, to bring a drug to market without a final ruling on the validity of Glaxo's patents allowed it to capture a large reward. The lesson here is that the statutory protection of the 180-day exclusivity period is not needed if the generic firm is willing to assume the cost of litigation and take on the risk of patent infringement. Even without an FDA mandated period of exclusivity, a generic company can leverage an early approval into substantial profits.

G. Glaxo's Response to Generic Entry: July to October

In response to Geneva's entry to the Augmentin market, Glaxo raised the price on those Augmentin products that faced competition from Geneva's perfect substitutes.⁴⁸ This move reflects a strategy of splitting the Augmentin market into price-sensitive and price-insensitive consumers: price-sensitive consumers will purchase the cheaper, generic drug, while price-insensitive consumers will purchase the branded drug. Glaxo priced its version of Augmentin approximately forty percent above Geneva's generic version of the drug during this time period.⁴⁹

company after Geneva to get the final approval from USFDA, Ranbaxy was the last generic company to launch the product as it wanted to avoid any litigation risk.").

46. *Id.*

47. This was not a "first mover advantage" in the typical sense of the word. However, the period of exclusivity enjoyed by Geneva does underscore the possibility of profits for the first generic firm to enter the market.

48. In addition to the original Augmentin formulation, which I simply call "Augmentin," Glaxo had two other specialized formulations on the market: XR and ES. Neither XR nor ES faced competition from perfect generic substitutes until later, and neither is included in the data set used in this Comment.

49. As discussed *infra* Part I, upon entry of multiple generic firms, the price premium for branded Augmentin rose nearly 100%.

TABLE 3
PRICE PREMIUM FOR BRANDED AUGMENTIN
AS COMPARED TO GENERIC AUGMENTIN

	One Generic Firm in Market	Two Generic Firms in Market	Three Generic Firms in Market
Price Premium	42%	34%	89%

Glaxo's pricing strategy during this initial "duopoly period" was successful: apparently many consumers were prepared to pay, on average, an additional \$25 for the branded version of the drug instead of the generic version of the drug. As a result, Glaxo still grossed \$281 million for the four-month period following Geneva's entry. More interestingly, and despite the higher price, Glaxo also maintained a roughly two-thirds share of all prescriptions in the four months following Geneva's entry.

Glaxo likely was able to maintain its sales despite the higher price because Geneva was either unwilling or unable to meet the needs of the entire Augmentin market. As a result, the generic drug supply may not have satisfied consumer demand for the lower priced substitute. If this were the case, then consumers would be forced to take Glaxo's branded version. It is possible that some consumers might switch to a different drug altogether,⁵⁰ but as long as the price difference between branded and generic Augmentin remained low in dollar terms, it is unlikely that patients would go to the trouble to contact their physician, request a different antibiotic, and then return to the pharmacy to make the purchase. Consequently, there would be a relatively small loss of sales to other therapeutic agents. If Glaxo had a rough idea of Geneva's ability to manufacture generic Augmentin, it could choose to produce a profit maximizing amount, thereby engaging in a form of Cournot competition.⁵¹

A shortage of the generic drug also explains why state generic substitution laws did not completely erode Glaxo's market share. Generic substitution laws typically direct pharmacists to fill prescriptions with

50. Or more accurately, their doctors would choose to prescribe an antibiotic other than Augmentin.

51. In Cournot competition, firms compete on the basis of quantity instead of price. Each firm can pick a quantity to produce, and the total quantity produced by all firms determines the price. When there are a small number of firms on the market, it is possible for each firm to strategically select a quantity to maximize profits based on the anticipated behavior of the other firms. Cournot competition is a key part of oligopoly pricing.

the lower priced generic version of a drug if it is available.⁵² These laws come in two forms: permissive and mandatory. Permissive substitution laws give pharmacists the option of prescribing the generic drug when presented with a prescription written for the drug using the brand name instead of the active ingredient.⁵³ Michigan has a typical permissive substitution law⁵⁴:

When a pharmacist receives a prescription for a brand name drug product, the pharmacist may, or when a purchaser requests a *lower cost* generically equivalent drug product, the pharmacist shall dispense a lower cost but not higher cost generically equivalent drug product *if available in the pharmacy*, except as provided in subsection (3).⁵⁵

Subsection (3) of the Michigan law prevents a pharmacist from dispensing the generic version of the drug if the prescribing doctor has written “dispense as written” or “d.a.w.” on the prescription.⁵⁶

Some states remove all discretion from the pharmacist when deciding whether to fill a prescription with the branded or generic version of a drug. Minnesota has a typical mandatory substitution law:

When a pharmacist receives a written prescription on which the prescriber has not personally written in handwriting “dispense as written” or “D.A.W.,” . . . *and there is available* in the pharmacist’s stock a *less expensive* generically equivalent drug . . . then *the pharmacist shall*, after disclosing the substitution to the purchaser, dispense the generic drug, unless the purchaser objects.⁵⁷

In practice, mandatory and permissive substitution laws amount to the same thing because a pharmacist has a financial incentive to dispense the cheaper, but higher margin, generic drug.⁵⁸ Because pharmacists’ margins on generic drugs are generally higher than for branded drugs, a

52. Generic substitution laws have been enacted in forty-seven of fifty states as of December 2006. The states without such laws are Idaho, Louisiana, and Oklahoma. For an analysis of substitution laws, see Henry G. Grabowski & John M. Vernon, *Substitution Laws and Innovation in the Pharmaceutical Industry*, 43 LAW & CONTEMP. PROBS. 43 (1979).

53. For example, a prescription written for “Augmentin” instead of “amoxicillin/clavulanic acid.”

54. A proposal currently in the Michigan Legislature would change Michigan’s law from permissive to mandatory.

55. MICH. COMP. LAWS § 333.17755(1) (1979) (emphasis added).

56. MICH. COMP. LAWS § 333.17755(3) (1979).

57. MINN. STAT. § 151.21(3) (2006) (emphasis added).

58. See David Pauly, *The Extraordinary Fact About Today’s Drugstores*, BLOOMBERG.COM, Nov. 29, 2005, http://www.bloomberg.com/apps/news?pid=10000039&sid=a.9c33E64OIo&refer=columnist_pauly.

pharmacist operating under a permissive substitution regime almost always will choose to dispense the generic drug.

Both types of substitution laws have the qualification that the generic drug must be available for the substitution to take place. This qualification explains Glaxo's success in maintaining market share once Geneva entered the market. If Geneva did not have the manufacturing capacity to supply the market with the cheaper generic drug, it could not take full advantage of the substitution laws. Why might a generic firm like Geneva be wary of making an upfront investment in manufacturing capacity? One explanation is that it knew it would soon face competition from further generic entry. Based on the patent litigation, Geneva could anticipate that at least two additional generic firms—Teva and Ranbaxy—would enter the market. As a rough estimate, Geneva might predict it would ultimately have a one-third share of the market and make an appropriate upfront capital investment in manufacturing capacity. Under this assumption, any capacity beyond one-third of the market would go unused.⁵⁹

The combination of Glaxo's increased prices and Geneva's limited output resulted in only a small decrease in the average price per prescription paid by consumers. Despite generic competition, the overall average price for Augmentin, both branded and generic, was \$76.56 during this time period. In contrast, the average price from the corresponding four-month period in 2001, when Glaxo faced no competition, was \$78.65. This result is interesting because it is contrary to the idea that generic entry rapidly drives down prices for consumers. While the price of the *generic* drug is substantially lower than that of the branded drug, the average price paid by consumers as a whole is essentially unchanged from a year earlier.

This result emphasizes that generic manufacturing capacity must be considered when predicting the cost savings stemming from generic entry. Other factors, such as the uncertainty in the timing of the entry of other generic firms to the market, might have also led Geneva to make a lower investment in production capacity. If, for example, the firm knew it had 180 days of exclusivity, then the higher level of certainty in its profits might induce it to invest in a higher level of production capacity. It is interesting to note, however, that during the four months of duopoly competition, Geneva supplied almost exactly one-third of the Augmentin prescriptions, the same result as might be expected if it anticipated splitting the generic market with two other generic competitors.

59. The choice to make an investment in capacity to supply only one-third of the market may also help a generic firm coordinate pricing when there are a limited number of competitors in the market, and thus facilitate oligopoly profits.

This finding sheds new light on the interaction between generic and branded firms. A recent strategy used by branded pharmaceutical firms is to introduce an “authorized generic”⁶⁰ to the market at the same time the generic firm enters the market with 180 days of exclusivity.⁶¹ An authorized generic is actually the branded drug, produced by the branded manufacturer, and packaged for sale as a “generic,” either by the branded firm or by a licensed generic firm. Because the branded firm already has FDA approval under an NDA, it is free to enter the generic market without filing an ANDA. Thus, there is the potential for a generic firm to face competition even if it successfully establishes paragraph IV certification.⁶²

The presence of an authorized generic in the market erodes much of the value of the 180-day period of exclusivity. First, and most importantly, the generic firm cannot rely on generic substitution laws to rapidly gain market share because these laws are only indifferent to the source of the lower-priced generic. Thus, the first generic firm to market would face genuine competition during the 180-day period of exclusivity.

Second, with another player in the market from the start, it becomes more difficult for the initial generic firm to predict the ultimate division of the generic market. Further complicating the calculus, the branded firm that produces the authorized generic has the demonstrated capacity to supply the entire market for the drug. Thus, it becomes far more difficult for generic firms to create a situation that facilitates oligopoly pricing based on their own limited ability to produce a drug.⁶³ As a result, the presence of a branded generic hurts the profits of both the first generic firm and all subsequent generic firms that enter the market.

H. Who Benefits Most From the 180 Days of Exclusivity?

The behavior of firms in the Augmentin market provides a way to analyze which parties benefit the most from the 180-day exclusivity

60. This type of drug is also known as a “brand-generic.”

61. *See, e.g.,* Teva Pharm. Indus. v. Crawford, 410 F.3d 51, 52–53 (D.C. Cir. 2005).

62. *Id.* at 54.

63. There is some evidence that the generic firms entering the Augmentin market were poised to compete on the basis of quantity instead of price. *See* EPP News Bureau, *supra* note 45 (“Ranbaxy has . . . a market share of less than 0.5 per cent even six weeks post launch of the oral dosage of generic Augmentin. This is because Teva has filled the supply chain with its product [after entry in December 2002] . . . Ranbaxy faces no input constraint for this product and it makes little sense for Teva to continue this strategy as this would then force Ranbaxy to cut prices significantly.”). Interestingly, the only suppliers of clavulanic acid, a key component of Augmentin, at the time of the generic transition were Glaxo, Novartis (Geneva), and DSM. Since DSM was the only independent supplier of clavulanic acid, one analyst commented “we do not believe that much competition is expected in this drug.” *Id.*

period granted to the first generic entrant. While the grant of exclusivity is justified as an incentive to induce generic firms to undertake litigation and bring products to market, these results suggest that it also provides a substantial benefit to the branded pharmaceutical maker. While Glaxo sold thirty-nine percent fewer prescriptions, its total revenue only declined by thirty-seven percent. Thus, relative to the number of prescriptions it sold, Glaxo was actually making *more* than it did the previous year. The entry of a single generic firm exerted some price pressure, but Geneva was only able, or willing, to supply a third of the Augmentin market, leaving the remaining two-thirds of the market to Glaxo. Consequently, Glaxo was able to recoup some of the revenue lost from the reduced number of prescriptions through higher pricing. During the four-month period where Geneva and Glaxo were the only firms competing in the Augmentin market, the average price paid by consumers decreased only three percent from the corresponding period in the previous year. Consumers paid a substantially lower price for the drug only after multiple generic firms entered the market.

An additional observation about the initial period of generic entry is that 180 days of exclusivity may be an excessive incentive for generic firms to bring drugs to market. This is especially true when the market value of the branded drug is high. In the case of Augmentin, Glaxo derived more than \$1.6 billion dollars in revenue from the drug in 2001, the year before generic entry. In just four months (approximately 120 days), Geneva was able to gross \$124 million dollars from the sale of generic Augmentin. If Geneva was willing to make a larger upfront investment in production capacity, or set its prices slightly higher, then it might have made even more money. Even without the 180 days of statutory exclusivity, multiple generic firms filed suit to invalidate Glaxo's patents. Later, multiple firms brought generic versions of Augmentin to market, despite the threat of unresolved patent infringement litigation. Clearly, the statutory incentive for generic entry was not necessary in this situation.

In fact, the Augmentin results indicate that the 180-day exclusivity period might actually *delay* the arrival of generic drugs to the market. Since the first generic firm to gain FDA approval knows it will receive 180 days of exclusivity, it can wait for a final judgment in any patent infringement litigation instead of bringing its product to market while the outcome is still uncertain. In contrast, Geneva, anticipating that other generic firms would soon obtain approval for their products, entered the market immediately after the district court's decision. Geneva weighed the threat of a finding of infringement on appeal against the temporary

opportunity⁶⁴ to bring a generic form of Augmentin to market without competition from other generic firms and decided to bring the drug to market.

Geneva was forced to choose between exclusivity and the threat of a suit, and the result was entry immediately after the district court decision. Since the appeal to the Federal Circuit was decided on November 21, 2003, Geneva's "at risk" entry into the Augmentin market occurred more than a year earlier than if it was granted the protection of the 180-day exclusivity period. The fact that Geneva's entry triggered other generic firms to enter the Augmentin market by January 2003 means that consumers enjoyed competition in the generic segment of the Augmentin market roughly seventeen months earlier than if Geneva were granted the exclusivity bounty.⁶⁵

The lesson learned from the period of duopoly competition in the Augmentin market is that generic firms will compete for entry without a 180-day exclusivity bounty as long as the market for the branded drug is large. While the 180-day bounty might make more sense for drugs with a relatively small market, it does not appear necessary to stimulate generic entry into the market for "blockbuster" drugs like Augmentin. If the generic entrant cannot produce the quantity of the drug demanded by the market during the 180-day exclusivity period, a segmented market will result. As a result, some consumers will pay lower prices for the generic, while others will pay higher prices for the branded drug. The net effect is that a single generic firm in the market for a drug may only yield a small reduction in the average price paid by consumers.

This analysis suggests that society should not expect a substantial change in the deadweight loss associated with monopoly pricing during the 180-day exclusivity period following paragraph IV FDA approval. If the 180-day period is to be justified, it must be as a means to induce entry that would not otherwise occur—the straight bounty for litigation—and not by any anticipated social gain. However, the Augmentin result also demonstrates that if the market is large, no bounty is needed to induce either litigation or generic entry. While the 180-day period of exclusivity might be relevant for drugs with smaller markets, it is unnecessary for blockbuster drugs.

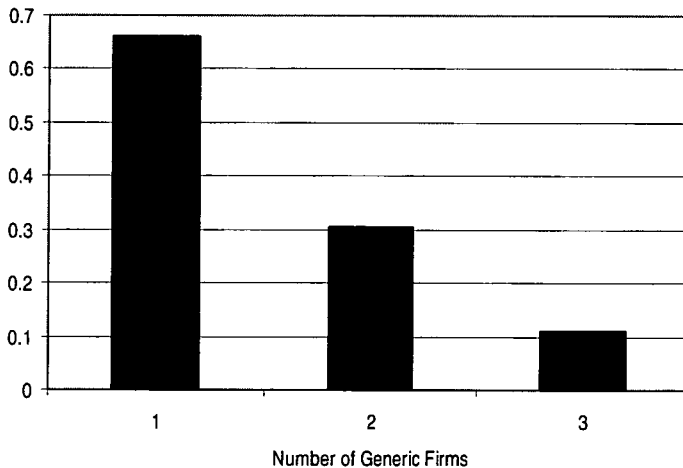
64. It is temporary because the Augmentin duopoly would last only until another generic version of the drug was approved for a firm brave enough to risk an infringement suit.

65. The seventeen-month estimate takes into account the November Federal Circuit decision plus the 180 days of exclusivity. In fact, this might be a conservative estimate if, for example, Geneva did not bring its generic drug to market immediately following the Federal Circuit decision. Here, Geneva sought to maximize the advantage it gained by being the first generic firm to gain FDA approval by bringing its product to market as early as possible.

I. More Generic Entry: How Many Generic Firms Are Needed to Bring Down Prices?

A single generic firm that anticipates further generic entry, and is therefore unwilling to invest in excess manufacturing capacity, is insufficient to yield substantially lower drug prices. The obvious question is how many generic firms are needed to significantly reduce the average price per prescription for the market as a whole. The answer, at least for Augmentin, is relatively few. After Geneva entered the market, Glaxo provided approximately sixty-six percent of all Augmentin prescriptions. Once Teva brought its generic version of Augmentin to market, Glaxo only maintained a thirty percent share of the Augmentin market.⁶⁶ Once Ranbaxy brought its version of Augmentin to the market, Glaxo captured only a little over ten percent of the market.⁶⁷

FIGURE I
GLAXO MARKET SHARE (%Rx)
AS A FUNCTION OF THE NUMBER OF GENERIC FIRMS IN THE MARKET



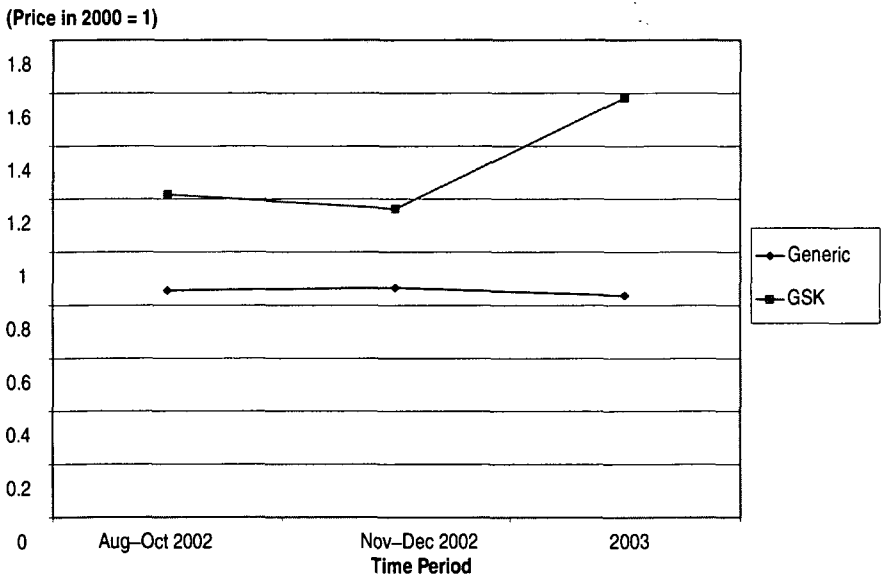
66. This reflects the two-month period, from November 2002 to December 2002, where there were two generic firms in the market. Again, it is interesting to note that the two generic firms together supplied two-thirds of the market, leaving the final third to Glaxo. If the two firms anticipated a third firm in the market, it would make sense that each projected a one-third market share for itself. This is in line with the data discussed *supra* Part G regarding Geneva's capacity during the duopoly period.

67. This number is the average over 2003, since Ranbaxy brought its version of Augmentin to market in January. However, Glaxo's market share declined throughout the year, and it only averaged a market share of eight percent of prescriptions over the final four months of 2003.

While Glaxo's market share was declining, its price for Augmentin was increasing. With one firm in the market, Glaxo sold its Augmentin at roughly 1.2 times the price it charged during the corresponding time period in 2000. With two firms in the market, Glaxo's relative price actually declined to 1.16 times the price in 2000. This decrease may be due to an unexpectedly rapid entry by Teva, resulting in a lower than anticipated demand for branded Augmentin. In other words, Glaxo might have incorrectly anticipated how many prescriptions Teva and Geneva combined could fill and produced too much branded Augmentin, leading to lower prices than when a single generic firm was in the market. Finally, with three firms in the market starting in January 2003, Glaxo's average price per prescription increased to 1.6 times 2000 levels.

With three generic firms in the market, Glaxo was left with two groups of consumers: the extremely price-insensitive consumers who refused to take generic versions of the drug, and the consumers whose doctors had indicated that the drug should be "dispensed as written" on the prescription, thereby preventing generic substitution. The former consumers were willing to pay high prices while the latter were forced to pay high prices because of generic substitution laws and because the actor making the purchasing decision, the doctor, does not have to pay for the product.

FIGURE 2
PRICE PER AUGMENTIN RX, NORMALIZED



Instead of dropping its price to compete with the generic products, Glaxo raised its prices to take advantage of the "captured" market. In the duopoly situation, the size of the "captured" market was related to the inability of a single generic firm to supply the entire demand for Augmentin prescriptions. Later, after subsequent generic entry created a situation where generic suppliers could fully meet consumer demand, the "captured" market becomes the combination of price-insensitive customers and patients whose doctors directed that the branded drug must be dispensed. Because of the price insensitivity of this group of consumers, Glaxo could maximize its profits by raising the price on its product dramatically. This leaves the price-sensitive portion of the market to the generic producers.⁶⁸

Faced with a choice between maximizing profits in the captive, cost-insensitive portion of the market and competing with generic firms for the overall market, Glaxo chose the former course of action. Generic substitution laws likely influenced this choice, which effectively force substitution whenever a generic is priced lower. These laws make it unlikely that a branded drug, even if it is only marginally more expensive than the generic drug, could capture much more than the price-insensitive share of the market. Absent the ability to price discriminate, it makes more sense to maximize profits within that price-insensitive segment and leave competition for the price-sensitive segment to the generic firms. Following this strategy, Glaxo eschewed price competition with the generic substitutes and raised the price on branded Augmentin to more than twice the generic level.

In 2003, Glaxo sold only nine percent as many prescriptions of Augmentin as in 2000. Despite the lower number of prescriptions sold, Glaxo was still able to gross \$185 million dollars from sales of Augmentin in 2003. Thus, the ability to charge price-insensitive consumers a much higher price allowed Glaxo to maintain a substantial market presence.

Interestingly, the entry of additional generic firms after the first had relatively little effect on the price of generic Augmentin. While prices were clearly lower as a result of generic entry, the normalized price charged⁶⁹ by the generic firm is roughly the same whether there are one (0.86 times 2000 prices), two (0.87 times 2000 prices), or three (0.84 times 2000 prices), generic firms in the market. The reason for the rela-

68. This phenomenon is not unique to Augmentin. It has been observed that the price of the branded drug generally increases with the advent of generic competition. See F.M. Scherer, *The Pharmaceutical Industry*, in 1 HANDBOOK OF HEALTH ECONOMICS 1297 (A.J. Culyer & J.P. Newhouse eds., 2000) (noting the increase in branded drug price post generic entry).

69. I use prices relative to the year 2000 to normalize for seasonal variations in demand that result in a sinusoidal pattern of pricing.

tively static pricing is unclear. While it is possible that the firms are pricing at marginal cost, which would leave little room for variation, this seems unlikely due to the small number of firms in the market. Instead, it could be that the firms are engaging in Cournot competition, which results in oligopoly pricing. Because there are only three firms in the price sensitive portion of the Augmentin market, and these firms are selling perfect substitutes, it is entirely possible that they are able to coordinate their output and pricing to achieve an oligopoly outcome.⁷⁰

The result is that even after generic entry, the decrease in the price per prescription will be limited if only a few firms enter the market. Even in the case of Augmentin, a billion dollar drug, only three distinct generic entities entered the market within the first year after Glaxo's patents were invalidated. Although generic Augmentin is cheaper than the branded drug (average price per prescription for generic Augmentin in 2003 was 0.84 times the average branded price in 2000), the extreme price increase of the branded version of Augmentin results in a smaller decline in the overall average market price paid by consumers (average price per prescription for all Augmentin, generic and branded was 0.92 times the average branded price in 2000). The moral of this part of the Augmentin story is twofold. First, the drop in price when generics enter may not be all that large because the market is ripe for coordinated pricing. Second, the increase in price of the branded drug significantly offsets the generic savings when the market is viewed as a whole.

CONCLUSION

The entry of generic firms into the Augmentin market provides an excellent system to study some of the strategic behavior that occurs at the end of a pharmaceutical's patent life. Moreover, since Augmentin was not included under the 1984 Hatch-Waxman provisions, it can serve as a control to observe the effect that the absence of a 180-day period of exclusivity has on generic entry. The Augmentin story suggests that generic entry might occur faster in the absence of the 180-day paragraph IV bounty because the first approved generic firm already has an incentive to enter the market as quickly as possible before other firms gain approval for their generic versions of the drug. Here, the threat of

70. Generic firms could also potentially divide a market through agreements to split the revenues from the 180-day exclusivity period, though this becomes substantially more difficult when an authorized generic is in the market. *See* *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 53 (D.C. Cir. 2005). The entry of an authorized generic puts generic firms in the unusual position of arguing that consumers are hurt by the presence of more competitors in the market. *See id.* at 54 (arguing that authorized generics prevent generic entry).

competition from Teva and Ranbaxy spurred Geneva to enter before a final judgment on the merits. This type of "at risk" entry is unlikely to occur if a firm is granted a 180-day exclusivity period.

The Augmentin story also suggests that generic firms have a considerable amount to lose from the entry of an authorized generic into the market. Dividing the market by output allows generic firms to keep prices above competitive levels via oligopoly pricing. The presence of an authorized generic, however, disrupts the ability of firms to use output capacity as a means to divide the generic portion of the market for a drug.

Finally, the Augmentin story suggests that the 180-day exclusivity period is far more complex than a simple incentive to stimulate generic entry. During the period of time where Glaxo and Geneva shared the Augmentin market, Glaxo was able to maintain a large share of the market and earn a considerable amount of revenue. While the 180-day exclusivity period certainly benefits the generic entrant, the Augmentin case study suggests that the branded producer also benefits during the period of generic exclusivity. Thus, despite lower prices within the generic segment of the market, consumers, on average, do not experience significantly lower prices due to the pioneer firm's move to increase prices on the branded drug.

In sum, the transition from exclusivity to generic competition is a very complicated situation with the opportunity for considerable strategic behavior by all parties involved. This Comment raises significant questions about whether the current system stimulates generic entry and the degree to which consumers benefit from this entry. Based on the results of this empirical analysis, policy makers might want to reconsider whether exclusivity is needed to induce generic entry and whether alternate incentives might lead to increased consumer welfare.